



# *News Release*

PO Box 360, Trenton, N.J. 08625-0360

Fred M. Jacobs, M.D., J.D.  
Commissioner

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For Further Information, Contact

(609) 984-7160

## **Department of Health and Senior Services Proposes to Amend N.J.A.C. 8:8-8.2 Addressing Donor's Emergency Care in the Rules Governing Collection, Processing, Storage and Distribution of Blood**

The Division of Public Health and Environmental Laboratories of the Public Health Protection and Emergency Preparedness Branch of the Department of Health and Senior Services is proposing to amend N.J.A.C. 8:8-8.2, Donor's emergency care, in the rules governing collection, processing, storage and distribution of blood. The notice of proposal to amend N.J.A.C. 8:8-8.2 appears in the October 3, 2005 issue of the New Jersey Register, as does a notice of readoption with amendments of N.J.A.C. 8:8.

The existing rules at N.J.A.C. 8:8 require "donor or transfusion emergency care personnel" required to be present on the premises during blood collection drives, to be either New Jersey licensed physicians or registered nurses holding a current registration certification. This requirement is often referred to as "the RN requirement" or the "nurse requirement." During the public comment period of the proposal to readopt the chapter, the Department received considerable public comment with regard to the proposed retention of the RN requirement. A summary of those comments appears in the notice of readoption with amendments of N.J.A.C. 8:8.

Upon review of the comments pertaining to the RN requirement, the Department convened a series of meetings with persons and entities interested in the issue in an attempt to seek a compromise. The proposed amendment is the result of those meetings. The proposed amendment would seek to provide blood centers with flexibility to conduct blood collections using emergency care personnel other than RNs under certain circumstances, while continuing to protect donors from potential harm resulting from emergencies arising during blood collection.

The proposed amendment would authorize blood bank directors to determine on a case-by-case basis with respect to each blood collection drive that a particular blood collection drive is exempt from the RN requirement provided that the blood bank has made a reasonable effort, in the manner specified in each blood bank's standard operating procedure (SOP), to schedule a physician or nurse for that blood drive and has determined that one is not available, and provided that the following conditions are met:

- The blood bank director has established an SOP outlining the requirements for granting an exemption from the emergency care personnel requirement and for the conduct of blood collection drives using alternative emergency care personnel, and that SOP is adhered to during the blood collection drive;
- Alternative emergency care personnel required to be present at the site of the blood collection drive meet training, education and experience requirements established in the SOP and, at minimum, possess current CPR and standard first aid certifications, and have

readily available either land line or cellular telephone communication access to immediately call 9-1-1 for assistance in the event of a medical emergency; and

- The blood bank maintains accurate records documenting all occurrences when the blood bank director had authorized an exemption to the RN requirement, including the date and location of the blood collection drive, the name and signature of the blood bank director who authorized the exemption, and the rationale for the blood bank director's determination that the blood collection drive is exempt from the RN requirement.

The proposed amendment would prohibit blood bank directors from determining that a blood collection drive is exempt from the RN requirement when blood is to be collected either from a group predominantly made up of high school aged students, or for the express purpose of autologous collection or maternal/fetal collection that is not conducted in a general hospital.

The proposed amendment also would authorize the Commissioner of Health and Senior Services or his or her designee to waive temporarily, for a period not to exceed 30 days, the RN requirement when the Commissioner or his or her designee determines that an emergent condition exists and that strict compliance with the RN requirement would prevent, hinder, or delay necessary action by the State to address the emergent condition, and would increase the health threat to the population. This provision would ensure that the Commissioner is able respond immediately to incidents or circumstances that might result in a critical shortage of blood available to meet the State's needs. The proposed amendment would also authorize the Commissioner or his or her designee to renew the waiver described above, by applying the standard for the initial waiver determination described above to the determination to renew the waiver.

The proposed amendment would require that during every blood collection drive, the blood bank conspicuously displays at the donor registration desk a sign, placard or other type of signage informing the donors of the name and qualifications (for example, licenses, certifications and training) of the emergency care personnel on duty and on site at the time of the blood collection drive. This provision would ensure that blood donors are appropriately aware of the qualifications of the blood bank personnel onsite at the blood drive responsible for providing emergency care that may be necessary.

The proposed amendment would limit the effectiveness of the provisions authorizing blood bank directors to authorize the use of alternative emergency care personnel to March 31, 2008, on which date they would expire. This provision would provide the Department with two years of data for review, thereby allowing the Department to assess and develop findings as to the impact of the proposed amendment authorizing blood bank directors to authorize the use of alternative emergency care personnel. The Department would share these findings with the interested persons and entities that participated in the stakeholder meetings discussed above and with the Public Health Council.

As stated above, the proposal appears in the October 3, 2005 issue of the New Jersey Register. The public has until December 2, 2005 to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Dennis P. McDonough, M.P.H., Director, Clinical Laboratory Improvement Service, Department of Health and Senior Services, Health and Agriculture Building, Room 405, P O Box 361, Trenton, NJ 08625-0361, Fax: (609)633-9601, Email: [Dennis.McDonough@doh.state.nj.us](mailto:Dennis.McDonough@doh.state.nj.us). Written comments must be postmarked, sent by telefacsimile, or sent by electronic mail on or before December 2, 2005, which is the close of the 60-day public comment period.

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